

Subject: Response to questions about Dr. Zhang
From: Kevin McCormack <KMcCormack@cirm.ca.gov>
Date: 3/28/19, 4:00 PM
To: "bradracino@inewssource.org" <bradracino@inewssource.org>

Hi Brad

Thanks for your patience.

Here's the answers to your questions. There's a lot of detail here so hopefully this helps.

1. What happens when CIRM is made aware of any problems within one of its sponsored studies while the study is ongoing?

This very much depends on the circumstances but always involves us working either with the researcher, the institution or the company involved on (1) identifying what the problem is, (2) what the underlying cause is, (3) and what are the proposed solutions. Our goal is to always ensure our funding is used in the way agreed upon with the applicant and that the research we fund is carried out with the highest scientific and ethical standards. If serious issues are identified, we have a number of options including halting funding for the project up to terminating the project and requesting the money we have already given be returned.

2. What happens when CIRM is made aware of any problems within one of its sponsored studies after the study has finished?

The above policy remains the same whether the award is still ongoing or is over.

3. Is CIRM made aware when government agencies discover wrongdoing with one of its sponsored grants? Is there any mandatory reporting?

Our policies require investigators or institutions to promptly report instances of non-compliance, academic misconduct or wrongdoing associated with any research or a researcher we are funding.

4. Does CIRM maintain a list of problematic researchers with whom they won't do business with in the future?

There is no list, but a researcher may be evaluated on their past performance. For example, a researcher's failure to meet milestones and other obligations on previous awards may be taken into account by reviewers when new applications are evaluated.

5. What was the goal with CIRM's funding the study, "Generation of fibroblast cell lines in patients with common blinding eye diseases AKA Collection of Blood or Skin Biopsy Samples from Patients with Late-Life Blinding Eye Disorders and from Healthy Matched-Controls for a Stem Cell Bank."

The study was part of the **Induced Pluripotent Stem Cell (iPSC) Repository**. The **Repository** is a CIRM infrastructure program to create a collection of stem cells developed from blood or skin biopsies from thousands of individuals. Dr. Zhang held one of the tissue collection awards to recruit donors with blinding eye diseases. CIRM created the iPSC bank so that scientists can use the cells, either in a petri dish or transplanted into animals, to study how disease develops and progresses and develop and test new drugs or other therapies. The large size of the collection will provide researchers with a powerful tool for studying genetic variation between individuals, helping scientists understand how disease and treatment may vary in a diverse population like California's.

6. Did that study hit all its "milestones" and receive full funding?

The study did not achieve its full donor recruitment goal, due to recruitment proving to be harder than expected, but a majority of samples were collected. The study did receive full funding, given funding was based on staff time and supplies.

7. Would CIRM work with Dr. Kang Zhang again, given the UCOP audit (attached) that found multiple problems with at least six of his human research studies, including the CIRM study?

If he were to apply to us for funding again, we would clearly review his application to ensure it met our standards and then require UCSD to sign off on the application and monitor compliance.

In addition she/he would have to meet the standards set out in our application form: https://www.cirm.ca.gov/sites/default/files/files/about_cirm/TRAN_PA_12.14.18_0.pdf

This states that in addition to the proposed project meeting our eligibility requirements the applicant must also meet our requirements. Specifically:

Applicant must be in “good standing.”

In order to be eligible to apply for CIRM funding an applicant must certify that it is in good standing as follows:

- a. For-Profit and Non-Profit (in existence for less than five years): (i) The applicant’s Chief Executive Officer, Chief Financial Officer, and Principal Investigator must not have been convicted of, nor currently under investigation for, crimes involving fraud/misappropriation; and (ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.
- b. All Applicants: (i) The Principal Investigator must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by HHS Office of Research Integrity

Cheers,

Kevin McCormack

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— Attachments: _____

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